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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/284,683 06/24/99 CEVC

G 500,1007

EXAMINER

023280 HM12/0420
DAVIDSON, DAVIDSON & KAPPEL, LLC
485 SEVENTH AVENUE, 14TH FLOOR
NEW YORK NY 10018

EXAMINER	PAPER NUMBER
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1615

DATE MAILED:

04/20/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 1-25-01

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☐ Claim(s) 1, 3-13 & 15-52 is/are pending in the application.
- ☐ Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 3-13 & 15-52 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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DETAILED ACTION

The request for the change of address dated 12-20-00, and the request for the extension of time and amendment dated 1-25-01 are acknowledged.

Claims included in the prosecution are 1,3-13 and 15-52.

Claim Rejections - 35 U.S.C. § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 3-13 and 15-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amended claim 5 does not appear to be grammatically correct. Applicant deletes the terms 'to permeates' which was between 'preparation' and 'through'.

Claims 11, 12 and 15 still contain improper Markush members, overlapping compounds and terms such as 'such', 'such as', 'corresponding'. Furthermore, these claims are so lengthy and it is not easy to follow the claims with all the additions and numerous deletions (also other claims). A clean copy has not been submitted.

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The examiner had already suggested a careful revision of these claims and restructure the claims.

Claim Rejections - 35 U.S.C. § 102

- 2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 3. Claims 1, 3-52 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0220 797 or Roberts (4,921,706) of record, or Mayer (BBA, 1986) of record, Blume (j. Of Liposome Research, 1992) of record, or EP 0 707 847 (Bayer) of record or EP 0 704 206 (Regenold) of record.**

EP discloses liposomes containing a drug, an amphiphilic lipid and a surfactant in instant amounts and a method of preparation (note the abstract, column 1, examples and claims).

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Similarly Roberts, Mayer, EP 847 and EP 206 all teach liposomes containing an amphiphilic lipid and a method of preparation (note the abstract and Materials & Methods section in both Roberts and Mayer; whole documents of EP).

Blume and EP 160 teach transfersomes and a method of preparation (note the entire documents).

Applicant's arguments have been fully considered, but are found to be persuasive. Applicant argues that the references teach liposomes and not transfersomes. A careful review of the examples in the specification shows that the methodology used in the preparation of instant composition is the same as the classical method of preparation of liposomes using one or more amphipathic lipids. The method involves making a film of the amphipathic lipids and hydrating the film. Instant claims recite numerous lipids (see the dependent claims) which are known lipids in the method of making liposomes. The examiner is unable to determine the differences between instant composition and those in EP references cited since there are no translations.

Claim Rejections - 35 U.S.C. § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. **Claims 1, 3-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 220 797, or Roberts (4,921,706) of record, or Mayer (BBA, 1986) of record, Blume (j. Of Liposome Research, 1992) of record, or EP 0 707 847 (Bayer) of record or EP 0 704 206 (Regenold) of record.**

As pointed out above, the references teach liposomes or transfersomes containing a drug, an amphiphilic lipid and a surfactant in instant amounts and a method of preparation. It is unclear whether the references teach all the instant functional parameters. In case they are different, in the absence of showing the criticality, they are deemed to be parameters manipulatable by an artisan to obtain the best possible results.

Applicant primarily argues that none of the references teaches transfersomes which undergo sufficient deformation to transport through skin or mucous membranes without being solubilized. This argument is not found to be persuasive for the reason that applicant's composition appears to be made from multitudes of the lipid components (see instant claims 11 and 12) which are art known liposome components and as pointed out above, prepared by the same liposome methodology. Furthermore, applicant himself has not shown that the composition prepared by numerous permutations and combinations possible with various lipids claimed behave the same way. Applicant's arguments thus, are not convincing.

6. **Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See**

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MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

April 19, 2001